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**Summary of Safety and Effectiveness****Submitter:**

Zimmer, Inc.  
P.O. Box 708  
Warsaw, IN 46581-0708

**JUL 24 2006****Contact Person:**

Patricia Jenks  
Specialist, Regulatory Affairs  
Telephone: (574) 371-8354  
Fax: (574) 372-4605

**Date:**

June 23, 2006

**Trade Name:**

*VerSys*® Fiber Metal MidCoat Low Head Center  
Hip Prosthesis

**Common Name:**

Total Hip Prosthesis

**Classification Name  
and Reference:**

Prosthesis, Hip, Semi-Constrained, Metal/Polymer  
Porous, Uncemented

Prosthesis, Hip, Semi-Constrained,  
Metal/Ceramic/Polymer, Cemented or Non-Porous,  
Uncemented

21 CFR § 888.3358, 888.3353

**Predicate Device:**

*VerSys* Beaded MidCoat Low Head Center Hip  
Prosthesis, manufactured by Zimmer, K042776,  
cleared November 4, 2004

**Device Description:**

Like its predicate, the *VerSys* Fiber Metal MidCoat Low Head Center Hip Prosthesis is a cementless, straight, modular femoral stem. The proposed and predicate devices are designed with trapezoidal geometry and feature 12/14 Morse-type proximal neck tapers to mate with the corresponding 12/14 bore of a femoral head component. Both devices feature 125-degree neck angles and distal, longitudinal splines. The modified device is manufactured from *Titanium*® Alloy and has circumferential, commercially-pure titanium fiber

metal pads for biological fixation.

**Intended Use:**

Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis; disability due to previous fusion; previously failed endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures.

Hemi-hip replacement for the following: fracture dislocation of the hip; elderly, debilitated patients when a total hip replacement is contraindicated; irreducible fractures in which adequate fixation cannot be obtained; certain high subcapital fractures and comminuted femoral neck fractures in the aged; nonunion of femoral neck fractures; secondary avascular necrosis of the femoral head; pathological fractures of the femoral neck; and osteoarthritis in which the femoral head is primarily affected.

**Comparison to Predicate Device:**

The modifications to the *VerSys* Fiber Metal MidCoat Low Head Center Hip Prosthesis change neither the intended use nor the fundamental scientific technology of the device as compared to the predicate. The modified and unmodified device use the same materials and processes for packaging and sterilization.

**Performance Data (Nonclinical and/or Clinical):**

Non-clinical performance testing demonstrated that the device is equivalent to the predicate.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Zimmer, Inc.  
c/o Patricia Jenks  
Specialist, Regulatory Affairs  
P.O. Box 708  
Warsaw, Indiana 46581-0708

JUL 24 2006

Re: K061786

Trade/Device Name: *VerSys*® Fiber Metal MidCoat Low Head Center Hip Prosthesis

Regulation Number: 21 CFR 888.3358

Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated  
uncemented prosthesis

Regulatory Class: Class II

Product Code: LPH

Dated: June 23, 2006

Received: June 26, 2006

Dear Ms. Jenks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", written in a cursive style.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K061786

## Indications for Use

510(k) Number (if known):

Device Name:

VerSys® Fiber Metal MidCoat Low Head Center Hip Prosthesis

### Indications for Use:

Total hip replacement for the following: severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, nonunion of previous fractures of the femur; congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis; disability due to previous fusion; previously failed endoprostheses, and/or total hip components in the affected extremity and acute femoral neck fractures.

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Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Barbara Smith*

(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

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